APHIS Risk Considerations on Importation of Classical Swine Fever (CSF) Virus in Breeding Swine, Swine Semen, and Fresh Pork from a European Union Region of Fifteen Member States

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Veterinary Services
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Executive Summary

In April 2003 APHIS, VS, published a final rule recognizing much of the European Union (EU) as a region in which classical swine fever (CSF) is not known to exist [1]. This region included the Member States of Austria, Belgium, Germany (with the exception of designated *kreis*), Greece, Italy (with the exception of the Island of Sardinia and the Regions of Emilia-Romagna and Piemonte), the Netherlands, and Portugal. This rule did not address the Member States of Denmark, Finland, Republic of Ireland, Sweden, or the United Kingdom (England, Scotland, Wales, Isle of Man, and Northern Ireland), which had previously been recognized as regions in which CSF was not known to exist [2, 3]. In addition, it did not address the Member States of France, Spain, Luxembourg, and designated *kreis* in Germany because those Member States or regions had experienced recent CSF outbreaks.

The decision-making process for the proposed rule and the recognition of specific Member States in the final rule were based primarily on the results of an eleven factor analysis summarized in the preamble a proposed rule [4], two risk analyses [5, 6] conducted by APHIS, and on information solicited under the requirements of the Administrative Procedure Act (APA) [7] as they applied to APHIS rulemaking. The first risk analysis [5] was released at the time of publication of the proposed rule in 1999 [4]. The second risk analysis, entitled *Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union – December 2000* [6], was released in 2002 for public comment and represented a revision and supplementation of the 1999 risk analysis. Data used in the risk analyses represented events that occurred during the 1997-1998 European CSF epidemic. This outbreak was considered the most severe ever experienced in Europe [8, 9]. The risk estimates reflected the assumption that CSF outbreaks would continue to occur in the region.

The previous eleven factor analysis of the region encompassing the seven Member States named in the 2003 rule and the estimates of risk in the risk analyses suggest that the EU control mechanisms are sufficiently effective to mitigate the risk of exporting CSF virus in breeding swine and pork and pork products to the United States. The risk analyses also suggested that the risk of exporting CSF in swine semen could be effectively mitigated with imposition of a 40-day post collection holding period in addition to existing EU control mechanisms prior to shipping semen to the US. This risk is low, despite the continued presence of infected wild boar in the EU and the expectation that CSF outbreaks will continue to occur in the EU.

Subsequently APHIS re-evaluated the CSF situation in France and Spain, releasing for public comment a supplemental risk analysis in November 2003 [10]. This supplemental risk analysis concluded that France and Spain have detection, control and eradication capacities similar to the EU Member States previously recognized as low-risk for CSF by the April 2003 final rule. A final rule was published on April 20, 2004, implementing the inclusion of France and Spain to the list of Member States recognized in the April 2003

rule [11]. With this rule, 14 of the 15 Member States comprising the EU prior to its May 2004 expansion were recognized as regions in which CSF was not known to exist.[1]

APHIS recognizes that CSF outbreaks are likely to continue to occur in the EU. However, because APHIS has concluded that the overall risk of exporting CSF in breeding swine, swine semen and fresh pork from the EU is low, APHIS intends to propose a novel approach to address CSF risk from all of the Member States constituting the EU in the year 2003 which are collectively referred to as European Union-15 (EU-15).[2] Luxembourg and certain regions in mainland Italy and Germany were previously excluded[3] from the list of regions that APHIS recognized as regions in which CSF was not known to exist because there had been recent CSF outbreaks in domestic swine. The Island of Sardinia had been excluded because of the high level of CSF that had been endemic in wild boar over a long period of time. However, in view of the result that APHIS considers the EC control measures as sufficient, APHIS proposes to include these regions in the proposed single EU-15 region. The proposed rule would change the regulatory process for one animal disease (CSF) and for one newly identified region:

- The EU-15 would be recognized as a single region for CSF;
- Restrictions that were imposed on exports of live swine, swine semen, and pork and pork products in the April 2003 final rule recognizing all or portions of twelve EU Member States as a region in which CSF is not known to exist will be applied to the EU-15 are adopted in this rule;
- European Commission (EC)[4] quarantine decisions with respect to areas affected by classical swine fever (CSF) would provide the basis for U.S. import restrictions imposed and removed with respect to that disease; and
- The competent veterinary authority of the EU-15 Member State would certify that the appropriate control measures, including both the EU and U.S. requirements, had been applied.

[1] In May 2004, the EU expanded to include the ten new Member States of the Czech Republic, Cyprus, Estonia, Hungary, Lativa, Lithuania, Malta, Poland, Slovakia, and Slovenia. This document and its associated proposed rule only address the 15 Member States comprising the EU prior to this expansion.

[2] European Union-15 (EU-15) is defined as including the Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. New EU Member States will be evaluated separately.

[3] APHIS previously excluded the entire territory of Luxembourg; the Island of Sardinia and the Regions of Emilia-Romagna and Piemonte in Italy; and in Germany, Kreis Uckermark in the Land of Brandenburg, Kreis Oldenberg, Kreis Soltau-Fallingbostel, and Kreis Vechta in the Land of Lower Saxony, Kreis Heinsberg and Kreis Warendorf in the Land of Northrhine-Westphalia, Kreis Bernbastel-Wittlich, Kreis Bitburg-Prum, Kreis Donnersbergkreis, Kreis Rhein-Hunsruche, Kreis Sudliche Weinstrasse, and Kreis Trier-Saarburg in the Land of Rhineland Palatinate, and Kreis Altmarkkreis in the Land of Saxony-Anhalt.

[4] The European Commission (EC) is the EU institution responsible for representing the EU as a whole. It proposes legislation, policies and programs of action and implements decisions of the EU Parliament and Council.

The April 2003 final rule did not address the five Member States previously recognized as regions in which CSF was not known to exist. As such, the rule had the effect of creating two regions within the EU from which swine and swine products may be exported. The first region, consisting of Denmark, Finland, Republic of Ireland, Sweden, and the United Kingdom, is a CSF-free region from which live swine, swine semen, and pork and pork products can be exported to the United States without any CSF-related restrictions. The second region, consisting of the Member States and portions of Member States recognized in the April 2003 final rule, is a CSF-free region for which CSF-related restrictions apply, limiting exports to the U.S. to breeding swine (no other live swine being eligible), swine semen, and pork and pork products. However, because of the free trade practices in the EU and the fact that the EU regulations apply uniformly to all Member States, APHIS considers the risk to be similar for both groups. Therefore, APHIS proposes to recognize the EU-15 as a single region for which import restrictions are uniformly applied. APHIS intends to standardize regulations for both of these groups in its current proposal.

The APA and the structure of the current regulations require that APHIS remove regions previously considered CSF free that experience a CSF outbreak from the list of CSF free regions with an interim rule. Prior to reinstatement, APHIS must solicit public comment on its intention to reinstate the designated regions. This structure requires that APHIS solicit comment either through proposed rulemaking or release of a risk analysis on the region. The new proposal will allow the public to comment on a novel approach in which public comment on individual regions is not solicited prior to reinstatement of freedom after a CSF outbreak in region of the EU-15. Rather, public comment will be solicited on the new process. APHIS considers the CSF risk presented by the EU-15 to be sufficiently low to justify this approach.

Under the proposed procedure, EU-15 regions that have an outbreak in domestic swine will not be removed from the list of CSF-free regions in 9 CFR 94.9 and 94.10 by interim rule, unless APHIS suspects that EU control measures are not effectively controlling a CSF outbreak. Rather, APHIS would rely on the EC to define and maintain restricted zones. Since the smaller, delimited regions, defined by EC quarantine restrictions because of a CSF outbreak, can (and probably will, based on the expectation that CSF outbreaks will continue to occur) remain a part of the entire region, the EU-15 can not be considered a "CSF-free" region. Despite the fact that the region can no longer be considered to be CSF-free under the new procedures, APHIS has determined that the risk of exporting breeding swine, swine semen, and fresh pork from the region is low. Therefore, APHIS is proposing to apply an administrative approach to removal of restrictions placed because of CSF occurrences in the region. The approach constitutes a significant departure from previous practices.

The conclusion that the risk was low was based on prior evaluations of EU-15 Member States either individually prior to formation of the EU or as a group of twelve in 2000. For that reason, we are limiting this proposal to the fifteen Member States (EU-15) that APHIS has evaluated. This region has the following characterics:

1. There is a known source of disease risk (e.g., infected wild boar) that may spread the virus to domestic swine resulting in continuing CSF outbreaks in the region, but in which veterinary officials have risk mitigation measures in place that are adequate to prevent widespread exposure and/or establishment of the disease;

2. Specific mitigation measures in place and required by EC regulation [12-14] include surveillance, epidemiological investigations, diagnostic capability, and emergency response capacity are sufficient to identify the disease, establish appropriate control zones, and implement all measures necessary to effectively limit spread of the disease out of the affected region;

3. Veterinary officials maintain contingency plans, as required by EC regulations, defining proactive approaches to CSF control: the veterinary officials must have sufficient legal powers, a detailed chain-of-command, and appropriate resources, including emergency funds, laboratory staff, equipment and infrastructure, necessary to carry out a rapid and effective eradication campaign; there must be an instruction manual detailing all procedures, instructions, and measures, including emergency vaccination plans if deemed necessary, to be implemented in the event of a CSF outbreak; and appropriate staff must regularly receive training and conduct drills in CSF diagnosis, control measures, and communication techniques [12, 13].

With the expectation that CSF outbreaks will continue to occur in the EU, APHIS proposes to recognize restriction zone boundaries for CSF that are established under EU legislation. APHIS defines the restriction zone to encompass protection and surveillance zones established around CSF outbreaks in domestic swine and to encompass infected zones established around outbreaks of CSF in wild boar (referred to in EU legislation as “feral pigs”) as prescribed in Council Directive 2001/89/EC [12, 13]. Definition and maintenance of the integrity of those zones will be the purview of the EC.

On a geographic basis, APHIS will recognize the regionalization decisions of the EC. However, APHIS will not accept commodities from a restriction zone implemented by the EC because of an outbreak in domestic swine until six months have elapsed (rather than 30 days, as allowed by EU legislation) following the depopulation, cleaning, and disinfection of the last infected premises. This restriction is considered necessary to ensure that disease has been eradicated from the zone and is unlikely to re-appear. It is based on observations that are discussed subsequently in which regions from which restrictions had been released 30 days after disease was stamped out were found to be infected shortly thereafter or regions from which infected animals were shipped after restrictions were lifted [15-18]. APHIS will recognize the duration of restrictions as imposed by the EC upon an infected zone because of detection of CSF in a wild boar population. The criteria used to determine when to release restrictions implemented in an infected zone are detailed in the EC-approved eradication plans for CSF in wild boar [12, 13].

To ensure that the commodities are not exported from regions that the EC has designated as affected (restriction and infection zones), APHIS proposes to require certification by

the competent veterinary authority of the EU-15 Member State that exported commodities do not originate from such regions. In addition, APHIS proposes to require that the competent veterinary authority of the EU-15 Member State certify to certain risk mitigating measures that were established on the basis of the APHIS 2000 Risk Analysis [6].

Summary of requirements (restrictions) for export to the US

In summary, APHIS will address CSF risk from the EU-15 using the following approach:

1. It will expand the scope of the restrictions defined in the April 2003 final rule (and described subsequently in this document as mitigations for pork and pork products, breeding swine, and swine semen) to all EU-15 Member States [19, 20].

2. It will require the competent veterinary authority of the EU-15 Member State to provide certification that the swine exported to the United States or the swine from which exported products were derived had never lived in a region when the region was classified as one in which CSF is known to exist. This certification will apply the EC definition of the borders of the relevant region as a restricted zone and recognize EC authority to maintain adequate controls as described subsequently in this document under the heading, *EU animal health controls*, within and around that zone. Specifically, the restriction zone will encompass protection and surveillance zones established around CSF outbreaks in domestic swine and to encompass infected zones established around CSF outbreaks in wild boar [12-14, 21].

3. For the purposes of export to the United States, it will require the competent veterinary authority of the EU-15 Member State to certify that no commodities originated from a restriction zone established because of CSF in domestic swine for a period of 6 months.

Introduction

In April 2003 APHIS, VS, published a final rule recognizing much of the European Union (EU) as a region in which classical swine fever (CSF) is not known to exist [1]. This region included the Member States of Austria, Belgium, Germany (with the exception of designated *kreis*), Greece, Italy (with the exception of the Island of Sardinia and the Regions of Emilia-Romagna and Piemonte), the Netherlands, and Portugal. This rule did not address the Member States of Denmark, Finland, Republic of Ireland, Sweden, or the United Kingdom (England, Scotland, Wales, Isle of Man, and Northern Ireland) because these regions were already recognized as CSF free at the time. In addition, it did not address the Member States of France, Spain, Luxembourg, and designated *kreis* in Germany because those Member States or regions had experienced recent CSF outbreaks.

In accordance with the rulemaking process requirements of the Administrative Procedure Act (APA) [7], APHIS proposed and finalized a rule recognizing specific Member States, basing these actions primarily on considerations of the eleven factors in the region summarized in the preamble to the proposed rule [4] and two risk analyses conducted by APHIS [5, 6]. The first risk analysis was released at the time of publication of the proposed rule in 1999 [4, 5]. The second risk analysis, entitled *Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union – December 2000* [6], was released in 2002 for public comment and represented a revision and supplementation of the 1999 risk analysis. Data used in both risk analyses represented events that occurred during the 1997-1998 European CSF epidemic. This outbreak was considered the most severe ever experienced in Europe [8, 9].

The analyses estimated the risk to the United States of CSF from the EU to be low. This estimate reflected the continuing presence of a CSF reservoir in infected wild boar (referred to as “feral pigs” in EU legislation) in the region as well as sporadic outbreaks in domestic swine.

APHIS assumes that risk estimated for the EU region that contains infected wild boar and continues to experience outbreaks (which will be called the new EU region) was greater than that estimated for the five EU Member States that were originally recognized as free (which will be called the former EU region). However, once the EU was formed and internal borders opened, the risk should be the same throughout.

The continuing outbreaks in domestic swine in the new EU region were reflected in the fact that the Member States named in the proposed rule differed from those named in the final rule because of several CSF outbreaks that occurred after publication of the proposed rule in 1999 [1, 4]. The APA did not allow APHIS to recognize as CSF-free Member States or regions within Member States in which an outbreak had occurred without providing an opportunity for public comment, even if the country or region had experienced no CSF outbreaks for several years. In this regard, the proposed rule had defined sub-national administrative units for Germany (*kreis*) and Italy (Region). This

allowed the final rulemaking to address these smaller units for these Member States but not for France, Spain, or Luxembourg where administrative units had not been defined.

Therefore, three Member States (France, Spain, and Luxembourg) and designated *kreis* in Germany were excluded from the final rule. Certain German *kreis* and Italian Regions that were excluded from the proposed rule were also excluded from the final rule.

Subsequently, APHIS re-evaluated the situation in Spain and France and when appropriate, intends to re-evaluate Luxembourg and the excluded regions in Germany and Italy. APHIS released a supplemental risk analysis, *APHIS Risk Analysis for Importation of the Classical Swine Fever Virus in Swine and Swine Products from France and Spain* [10]. A notice of availability requesting public comment on this analysis was published in the *Federal Register* on November 24, 2003 [22]. That analysis concluded that the magnitude of the outbreaks in France and Spain was less than the magnitude of the outbreaks in 1997 and 1998. Therefore, the estimated risk from France and Spain fell within the expectations of the earlier analysis and was no greater than that for the regions that had been recognized as free in April 2003. As such, the risk analysis supported adding Spain and France to that list of regions. A final rule was published on April 20, 2004, implementing the inclusion of France and Spain to the region recognized in the April 2003 rule [11].

APHIS considers that the evidence it has collected to date and the results of several analyses support the concept that the Member States constituting the EU in the year 2003, collectively referred to as the European Union-15 (EU-15),[5] is a region from which the risk of exporting CSF virus in breeding swine, swine semen and fresh pork to the United States is low. The estimates of risk in the risk analyses suggest that the EU control mechanisms are sufficiently effective to mitigate the risk of exporting CSF virus in breeding swine and pork and pork products to the United States. The risk analyses also suggested that the risk of exporting CSF in swine semen could be effectively mitigated with imposition of a 40-day post collection holding period in addition to existing EU control mechanisms prior to shipping semen to the US. This risk is low, despite the continued presence of infected wild boar in the EU and the expectation that CSF outbreaks will continue to occur in the EU.

Luxembourg and certain regions in Italy and Germany and were previously excluded[6] from the list of regions that APHIS recognized as regions in which CSF was not know to

[5] European Union-15 (EU-15) is defined as including the Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. New EU Member States will be evaluated separately.

[6] APHIS previously excluded the entire territory of Luxembourg; the Island of Sardinia and the Regions of Emilia-Romagna and Piemonte in Italy; and in Germany, Kreis Uckermark in the Land of Brandenburg, Kreis Oldenberg, Kreis Soltau-Fallingbostel, and Kreis Vechta in the Land of Lower Saxony, Kreis Heinsberg and Kreis Warendorf in the Land of Northrhine-Westphalia, Kreis Bernbastel-Wittlich, Kreis Bitburg-Prum, Kreis Donnersbergkreis, Kreis Rhein-Hunsruche, Kreis Sudliche Weinstrasse, and Kreis Trier-Saarburg in the Land of Rhineland Palatinate, and Kreis Altmarkkreis in the Land of Saxony-Anhalt.

exist because of recent CSF outbreaks in domestic swine. The Island of Sardinia in Italy had been excluded because of the high level of CSF that had been endemic in wild boar over a long period of time. However in view of the result that APHIS considers the EC control measures as sufficient, APHIS proposes to include these regions in the proposed single EU-15 region.

Objective

APHIS intends to propose a novel approach to address CSF risk from the EU-15. The proposed rule would change the regulatory process for one animal disease (CSF) and for one newly identified region:

- The EU-15 would be recognized as a single region for CSF;
- Restrictions that were imposed on exports of live swine, swine semen, and pork and pork products in the April 2003 final rule recognizing all or portions of twelve EU Member States as a region in which CSF is not known to exist will be applied to the EU-15 are adopted in this rule;
- EU quarantine decisions with respect to areas affected by classical swine fever (CSF) would provide the basis for U.S. import restrictions imposed and removed with respect to that disease; and
- The competent veterinary authority of the EU-15 Member State would certify that the appropriate control measures, including both the EU and U.S. requirements, had been applied.

The April 2003 final rule did not address the five Member States previously recognized as regions in which CSF was not known to exist. As such, the rule has the effect of creating two regions within the EU from which swine and swine products may be exported. The first region, consisting of Denmark, Finland, Republic of Ireland, Sweden, and the United Kingdom, is a CSF-free region from which live swine, swine semen, and pork and pork products can be exported to the United States without any CSF-related restrictions. The second region, consisting of the Member States and portions of Member States recognized in the April 2003 final rule, is a CSF-free region for which CSF-related restrictions apply, limiting exports to the U.S. to breeding swine (no other live swine being eligible), swine semen, and pork and pork products. However, because of the free trade practices in the EU and the fact that the EU regulations apply uniformly to all Member States, APHIS considers the risk to be similar for both groups. Therefore, APHIS proposes to recognize the EU-15 as a single region for which import restrictions are uniformly applied. APHIS intends to standardize regulations for both of these groups in its current proposal.

The APA and the structure of the current regulations require that APHIS remove regions previously considered CSF free that experience a CSF outbreak from the list of CSF free regions with an interim rule. Prior to reinstatement, APHIS must solicit public comment on its intention to reinstate the designated regions. This structure requires that APHIS solicit comment either through proposed rulemaking or release of a risk analysis on the

region. The new proposal will allow the public to comment on a novel approach in which public comment on individual regions is not solicited prior to reinstatement of freedom after a CSF outbreak in region of the EU-15. Rather, public comment will be solicited on the new process. APHIS considers the CSF risk presented by the EU-15 to be sufficiently low to justify this approach. It bases this on the results of the prior evaluations, which include an eleven factor summary [4] and two risk analyses [5, 6]. The conclusion from these evaluations was that CSF risk from the EU-15 was low, despite the expectation that CSF outbreaks would continue to occur in the region. The EU surveillance and control measures in place were considered sufficient to detect, contain, and eliminate any outbreaks, such as those that occurred in the excluded German kreis, Italian provinces, and Luxembourg.

With the expectation that CSF outbreaks will continue to occur in the EU, APHIS proposes to recognize restriction zone boundaries for CSF that are established under EU legislation. APHIS defines the restriction zone to encompass protection and surveillance zones established around CSF outbreaks in domestic swine and to encompass infected zones established around outbreaks of CSF in wild boar (referred to in EU legislation as "feral pigs") as prescribed in Council Directive 2001/89/EC [12, 13]. Definition and maintenance of the integrity of those zones will be the purview of the EC.

On a geographic basis, APHIS will recognize the regionalization decisions of the EC. However, APHIS will not accept commodities from a restriction zone implemented by the EC because of an outbreak in domestic swine until six months have elapsed (rather than 30 days, as allowed by EU legislation) following the depopulation, cleaning, and disinfection of the last infected premises. This restriction is considered necessary to ensure that disease has been eradicated from the zone and is unlikely to re-appear. It is based on observations that are discussed subsequently in which regions from which restrictions had been released 30 days after the disease was stamped out were found to be infected shortly thereafter or regions from which infected animals were shipped after restrictions were lifted [15-18]. APHIS will recognize the duration of restrictions as imposed by the EC upon an infected zone because of detection of CSF in a wild boar population. The criteria used to determine when to release restrictions implemented in an infected zone are detailed in the EC-approved eradication plans for CSF in wild boar [12, 13].

To ensure that the commodities are not exported from regions that the EC has designated as affected (restriction and infection zones), APHIS proposes to require certification by the competent veterinary authority of the EU-15 Member State that exported commodities do not originate from such regions. In addition, APHIS proposes to require that the competent veterinary authority of the EU-15 Member State certify to certain risk mitigating measures that were established on the basis of the APHIS 2000 Risk Analysis [6]. These certification requirements will apply to all EU-15 Member States. APHIS will also extend the restrictions described in the April 2003 final rule to the EU-15.

Background

Previous actions taken by APHIS relative to CSF in the European Union

Before April 7, 2003, APHIS recognized five EU Member States as regions in which CSF was not known to exist. APHIS had recognized each of these Member States as CSF-free prior to the establishment of the EU. [Note: although the eleven factors defined in 9 CFR 92.2 had not been implemented at the time of these evaluations, APHIS considers the results of the evaluation conducted to be equivalent to an eleven factor analysis.] As a result, the original evaluation conducted did not consider risk that might arise as a result of opening borders within the EU and the possibility that Member States that APHIS recognized as CSF-free would trade freely with other Member States that APHIS considered to be affected with CSF.

On April 7, 2003, APHIS published a final rule recognizing additional regions of the EU as regions in which CSF was not known to exist (also known as "CSF-free" under APHIS regulations existing in 2003) [1]. This rule was based on information provided by the European Commission [23], an eleven factor analysis [4] and a risk analysis, *Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union – December 2000,* conducted by APHIS [6]. The 2000 Risk Analysis included a quantitative estimate of the risk of introducing CSF infected breeding swine, swine semen and fresh or frozen pork into the US. The analysis for swine was limited to breeding swine because those were the only live swine exports that were considered economically feasible.

In the 2000 Risk Analysis, APHIS estimated the risk of introducing CSF by importing breeding swine as one or more incursions in an average of 33,670 years; for fresh or frozen pork, the estimate is one or more incursions in an average of 22,676 years. APHIS considered these risks to be low.

However, APHIS estimated the risk of introducing CSF by importing swine semen from the EU as one or more incursions in an average of 1,842 years. Since this risk appeared significantly greater than the risk estimated for either importing breeding swine or swine products, APHIS imposed the additional mitigation of holding swine semen donor boars and observing them clinically for 40 days after semen collection. This 40-day post-collection holding period is in addition to the 30-day holding period required by EU legislation before the animals may enter an approved EU semen center [24, 25]. The additional mitigation reduced the estimated risk associated with importing swine semen to one or more incursions in an average of 8,090 years. APHIS concluded that with mitigation the risk was low.

An underlying assumption of the analyses was that, because CSF was endemic in wild boar in several parts of the EU, outbreaks in domestic swine would continue to occur within the EU. To address this issue, APHIS included several risk mitigating measures in the final rule. Specifically, APHIS required the competent veterinary authority of the EU-15 Member State to certify (1) the origin of the commodities, (2) that commingling

did not occur, and (3) that swine semen was subjected to certain restrictions which will be described in more detail later in this document. While accepting the assumption that outbreaks would continue to occur, VS concluded that the veterinary infrastructure, and surveillance and control measures existing in the EU were sufficient to detect and control those outbreaks before infected animals or products could be exported to the US. APHIS imposed the mitigations to ensure that EU control measures were maintained.

The risk analysis did address the open borders of the EU and established requirements to segregate commodities from affected and unaffected regions and to ensure that semen donors are truly CSF-free. Because of the open borders in the EU, various mitigations were established for the EU Member States that were recognized as regions not affected with CSF after April 7, 2003.

Mitigations for pork and pork products that were required in this rule were the following:

1. The pork or pork products must not have been commingled with pork or pork products derived from swine that had been in any region when the region was classified as one in which CSF is known to exist;
2. The swine from which the pork or pork products were derived must not have lived in a region when the region was classified as one in which CSF is known to exist and must not have transited such a region unless moved directly through the region in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination; and
3. The pork and pork products must be accompanied by a certificate issued by an official of the national government of the region of origin who is authorized to issue the foreign meat inspection certificate required by FSIS.

Mitigations for live swine that were required in this rule were the following:

1. The swine must be breeding swine and must not have lived in a region when the region considered as one in which CSF is known to exist and must not have transited such a region unless moved directly through the region in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination;
2. The swine must never have been commingled with swine that were in a region at the time when the region was considered one in which classical swine fever is known to exist;
3. No equipment or materials used in transporting the swine may have previously been used for transporting swine that do not meet the requirements of this section, unless the equipment or materials have first been cleaned and disinfected; and
4. The swine must be accompanied by a certificate issued by a salaried veterinary officer of the national government of the country of origin stating the provisions have been met.

For swine and pork and pork products, the certificates must be presented by the importer to the appropriate officials at the port of arrival for inspection.

Mitigations for swine semen that were required in this rule were the following:

1. The semen must come only from a semen collection center approved for export by the veterinary services of the national government of the country of origin;
2. The donor boar must not have lived in a region when the region was classified as one in which CSF is known to exist and must not have transited such a region unless moved directly through the region in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination;
3. The donor boar must never have been commingled with swine that have been in a region when the region was considered as one in which CSF is known to exist;
4. The donor boar must be held in isolation for at least 30 days prior to entering the semen collection center;
5. No more than 30 days prior to being held in isolation the donor boar must be tested with negative results with a CSF test approved by OIE;
6. No equipment or materials used in transporting the donor boar from the farm of origin to the semen collection center may have been used previously for transporting swine that do not meet APHIS import requirements, unless first cleaned and disinfected;
7. The donor boar must be observed at the semen collection center by the center veterinarian and exhibit no clinical signs of CSF;
8. Before the semen is exported to the US, the donor boar must be held at the semen collection center for at least 40 days following collection of the semen, and, along with all other swine at the semen collection center, exhibit no clinical signs of CSF; and
9. The semen must be accompanied to the United States by a certificate issued by a salaried veterinary officer of the national government stating the above provisions have been met.

In summary, inconsistencies exist in current APHIS requirements for EU Member States that are recognized as regions in which CSF is not known to exist. Restrictions on Member States that were evaluated before the EU was formed are less stringent than those on Member States added to the CSF-free list after April 7, 2003. However, because of the free trade practices in the EU and the fact that the same regulations apply to all Member States, APHIS considers the risk to be similar for both groups. Concerns that applied to the Member States that were evaluated in 2000 should also now apply to those that were evaluated before formation of the European Union. APHIS intends to standardize regulations for both of these groups in its current proposal.

EU animal health controls

Animal health regulations imposed by the EU are harmonized and binding upon all Member States [12-14]. Requirements include compulsory notification of OIE List A diseases, including CSF, and laboratory testing for CSF on all sick swine if CSF is suspected.

Measures related to reservoir of CSF virus

In accordance with Articles 15 and 16 of Council Directive 2001/89/EC [12, 13], whenever CSF is detected in a wild boar, the veterinary authority, in consultation with an expert panel of veterinarians, hunters, wildlife biologists and epidemiologists, define the appropriate infected area, implement appropriate measures to reduce the spread of disease, develop and submit for EC approval an eradication plan, and audit the effectiveness of measures adopted to eradicate CSF from the infected area. These measures require that all domestic swine holdings in the infected area be placed under official surveillance, an official census be conducted, swine movement be restricted, biosecurity measures implemented, and testing for CSF is conducted on all sick or dead pigs. Furthermore, all wild boar shot or found dead must be examined and tested for CSF by an official veterinarian designated by the competent authority of the Member State. In addition, these measures may include suspension of hunting and a ban in feeding wild boar. The veterinary authority must also ensure that the CSF isolate is genetically typed. Adjacent Member States shall collaborate in establishing control measures in cases where the infected wild boar is found close to common borders.

As part of an approved eradication plan, emergency vaccination of wild boar may be introduced in situations where CSF has been confirmed and epidemiological data suggests that the disease threatens to spread [12, 13]. The vaccination area must be a part of the defined infected area, and appropriate measures must be taken to prevent spread of the vaccine virus to domestic pigs. Currently there is an ongoing emergency vaccination program for wild boar in infected areas within Germany and Luxembourg [26-28].

Measures to detect, control and eradicate CSF in domestic swine

Swine move freely between EU Member States and within Member States. Swine born in one Member State are routinely fattened or slaughtered in another. Animals moving between Member States are required to be accompanied by an official health certificate, issued by the official veterinarian appointed by the competent authority of the Member State, and prior notification of the movement is reported electronically through an electronic network linking veterinary authorities of the Commission and Member States [21, 29].[7]

Farm registration is mandatory and each holding is assigned a unique identification number by the competent authority of the Member State. Animal identification is compulsory requiring breeding swine to be identified with a unique identification number (either by ear tag or tattoo) and fattening swine to be identified using the holding registration number. This information is maintained by each Member State.

[7] TRACES (Trade Control and Export System) is replacing ANIMO, by the end of 2004, as the computerized system mandated by EU law to track animal and animal product movement between Member States as well as for tracking imports from third countries into the EU. Data are entered by local veterinary authorities within each Member Country and shared over a network with the rest of the EU. The system is administered by a private contractor with oversight by the EC and the EU Court of Auditors (discussed in [6]).

Once CSF is detected anywhere in the EU, control mechanisms are activated in accordance with EU legislation [12, 13]. When CSF is suspected on a pig holding, a clinical investigation is conducted to confirm or rule out the disease and an epidemiological investigation ensues. Movement of pigs from the holding under suspicion is prohibited and biosecurity measures are implemented to prevent the spread of disease.

Upon confirmation of CSF, depopulation of all swine on the infected holding is required and the carcasses are processed under official supervision. Protection and surveillance zones are established around an outbreak (minimum radius of 3 km and 10 km respectively from the outbreak site). According to EU legislation [12, 13], when establishing zones the veterinary authorities are required to take into account: (1) the results of the epidemiological investigation; (2) the geographical situation, particularly natural or artificial boundaries; (3) the location and proximity of holdings; (4) patterns of movements and trade in pigs and the availability of slaughterhouses; and (5) the facilities and personnel available to control any movement of pigs within the zones, in particular if the pigs to be killed have to be moved away from their holding of origin. Veterinary authorities shall take all necessary measures, including posting signs and alerting the media, to inform the public of the imposed restrictions, and will use appropriate measures to enforce the restrictions. Veterinary authorities of Member States will collaborate in establishing zones that overlap their borders.

Movement from the zones is restricted. Specifically, premises within the protection zone are prohibited from moving swine outside the zone for at least 30 days. Premises within the surveillance zone are prohibited from moving swine outside the zone for at least 20 days. A census is conducted for all swine in both the protection and surveillance zones. Clinical examinations are conducted on all pigs within the protection zone.

An epidemiological inquiry is made into the origin of the virus and contacts are identified for trace-back and trace-on investigations. Isolates of the virus are genetically typed by the EU Reference Laboratory in Hanover, Germany.

Under official supervision of the competent authority of the Member State, meat of pigs slaughtered during the period between the probable introduction of disease and the implementation of control measures is traced and processed in such a way as to destroy or inactivate the CSF virus. Likewise, swine genetic products collected during this time are traced and destroyed under official supervision in such a way as to avoid the risk of spread of CSF virus.

After depopulation, the buildings, equipment, vehicles, etc. that may have been contaminated with the CSF virus must be cleaned and disinfected under official supervision using approved disinfectants.

Reintroduction of pigs onto an infected holding shall not take place until at least 30 days after the cleaning and disinfection, and shall be monitored to be sure that none develop antibodies to CSF.

The EU currently does not vaccinate domestic pigs for CSF. However with EC approval, emergency vaccination may be used in cases where CSF has been confirmed and epidemiological data suggests that the disease threatens to spread [12, 13, 30].

Contingency plans for CSF control

Member States are required to have a contingency plan defining proactive approaches to CSF control [12, 13]. This plan must be approved by the Commission. In each Member State, veterinary officials must possess sufficient legal powers, a detailed chain-of-command, and appropriate resources, including emergency funds, laboratory staff, equipment and infrastructure, necessary to carry out a rapid and effective eradication campaign in the event of a CSF outbreak. The plan must include an instruction manual detailing all procedures, instructions, and measures, including emergency vaccination plans if deemed necessary, to be implemented in the event of a CSF outbreak. Appropriate staff must regularly receive training and conduct drills in CSF diagnosis, control measures, and communication techniques.

EU controls and future risk

In the APHIS 2000 Risk Analysis, the risk estimated was based on quantitative data reflecting the effects of EU regulations in place during a severe CSF outbreak in 1997 and 1998 that occurred extensively in The Netherlands and spread to other Member States. In fact, the outbreak, which is considered the most severe the EU has ever experienced, showed that EU regulations were not completely effective in that disease spread did occur. However, despite the limitations in EU control mechanisms, the quantitative estimates of risk to the United States were low. Therefore, future risk should be no greater than that estimated by the 2000 Risk Analysis (unless an outbreak occurred that was more severe than the one in 1997-1998) if we rely on EU controls.

Risk from wild boar

A primary assumption underlying the risk analysis was that CSF outbreaks will continue to occur in the EU. That assumption has proven true [Table 1. lists EU Member States in which outbreaks occurred in domestic swine since 1993].

Table 1. CSF Outbreaks in Domestic Pigs EU Member States between 1993 and 2003

1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Germany	Germany	Germany	Germany	Germany	Germany	Germany	Germany	Germany	Germany	Germany
Italy	Italy	Italy	Italy	Italy	Italy	Italy	Italy	Italy		Italy
Belgium	Belgium			Belgium						
France									France	
	Austria	Austria	Austria							
				Netherlands	Netherlands					
				Spain	Spain			Spain	Spain	
							UK			
									Luxembourg	Luxembourg

Source: OIE [15]

During the two-year period 1997-1998, the EU reported 653 outbreaks of CSF in domestic swine resulting in the death or destruction of over one-million swine [15]. This is compared with the three-year period of 2001-2003 in which the EU reported 86 outbreaks with just over 100,000 deaths or destroyed swine [15]. Of note is that the risk analyses results took into account the outbreaks documented in the table that occurred in 1997 and 1998. As previously mentioned, these were the most extensive observed during the entire reporting period. Even though the data used included information from the period during which the outbreaks were most extensive, the risk estimate was low.

APHIS initially proposed (1999) to recognize a significant portion of the EU[8] as a region in which CSF does not exist [4]. Before that rule was finalized, France, Spain, Luxembourg and certain *kreis*[9] in Germany experienced outbreaks of CSF in domestic swine. Therefore, in accordance with the APA and the current regulations which require public comment on APHIS intention to recognize as CSF-free a region in which an outbreak occurred, these regions were excluded from the final rule [1].

Subsequently APHIS re-evaluated the CSF situation in France and Spain, releasing for public comment a supplemental risk analysis in November 2003 [10]. This supplemental risk analysis concluded that France and Spain have detection, control and eradication capacities similar to the EU Member States previously recognized as low-risk for CSF by the April 2003 final rule. A final rule was published on April 20, 2004, implementing the inclusion of France and Spain to the list of Member States recognized in the April 2003 rule [11].

Although the estimates of CSF risk from the EU region identified in our 1999 and 2000 risk analyses were based on data related only to outbreaks and control measures in domestic swine (i.e. data from wild boar outbreaks were not included), APHIS recognizes that EU control measures implemented in response to outbreaks in wild boar had a mitigating effect on the spread of CSF in domestic swine. Therefore APHIS believes that

[8] Previously APHIS recognized five Member States (United Kingdom, Ireland, Denmark, Sweden, and Finland) as regions in which CSF is not known to exist.

[9] A *kreis* is the smallest administrative unit in Germany that is recognized by APHIS for the purposes of animal health regionalization [1, 4, 6].

EU control measures for CSF in wild boar are a critical component of the overall EU controls for CSF. In fact, wild boar continue to be a source of infection in domestic pigs. For example, infected wild boar are the suspected source of virus linked to the August 2003 outbreak in Luxembourg, the April 2002 outbreak in France and multiple outbreaks in Germany [18]. The EU recognizes the risk to its domestic swine population because of the endemic CSF infection in wild boar, and has implemented eradication plans and contingency measures to deal with this problem. To protect the domestic swine herd throughout the region, the EU has placed restrictions on movement of domestic swine out of the infected wild boar areas [12, 13, 31-34]. It is likely that the EU restrictions on regions containing infected wild boar contribute significantly to the effectiveness of EU control measures. APHIS will recognize the geographical boundaries of the controls imposed by the EC because of infected wild boar.

Proposed Action

The European Union-15 would be recognized as a single region for CSF

Under existing regulations, APHIS considers much of the EU as a region in which CSF is not known to exist, including the five Member States recognized as CSF-free prior to April 2003 and those Member States recognized in the April 2003 and any subsequent final rules. This consideration was based on the fact that the actions that APHIS had taken historically under the APA [7] in response to an outbreak in domestic pigs in the region would maintain the region as one in which CSF was not known to exist by removing affected regions. APHIS accomplished this by publication of an interim rule to remove regions that experienced an outbreak in domestic pigs from the list of regions not known to have CSF. The interim rule could remove either an entire country or an appropriately defined administrative unit from the list of CSF-free regions. Practically speaking, the remaining regions of the EU would be CSF-free.

Under the proposed procedure, EU-15 regions that have an outbreak in domestic swine will not be removed from the list of CSF-free regions in 9 CFR 94.9 and 94.10 by interim rule, unless APHIS suspects that EU control measures are not effectively controlling a CSF outbreak. Rather, APHIS would rely on the EC to define and maintain restricted zones. Since the smaller, delimited regions, defined by EC quarantine restrictions because of a CSF outbreak, can (and probably will, based on the expectation that CSF outbreaks will continue to occur) remain a part of the entire region, the EU-15 can not be considered a "CSF-free" region. Despite the fact that the region can no longer be considered to be CSF-free under the new procedures, APHIS has determined that the risk of exporting breeding swine, swine semen, and fresh pork from the region is low. APHIS is imposing restrictions appropriate for the region.

The conclusion that the risk was low was based on prior evaluations of EU-15 Member States, either individually prior to formation of the EU or as a single region in 2000. For that reason, we are limiting this proposal to the fifteen Member States (EU-15) that APHIS has evaluated. The region has the following characteristics:

1. There is a known source of disease risk (e.g., infected wild boar) that may spread the virus to domestic swine resulting in continuing CSF outbreaks in the region, but in which veterinary officials have risk mitigation measures in place that are adequate to prevent widespread exposure and/or establishment of the disease;

2. Specific mitigation measures in place and required by EU regulation [12-14] include surveillance, epidemiological investigations, diagnostic capability, and emergency response capacity are sufficient to identify the disease, establish appropriate control zones, and implement all measures necessary to effectively limit spread of the disease out of the affected region;

3. Veterinary officials maintain contingency plans required by Article 22 of Council Directive 2001/89/EC in which veterinary officials maintain contingency plans defining proactive approaches to CSF control: the veterinary officials must have sufficient legal powers, a detailed chain-of-command, and appropriate resources, including emergency funds, laboratory staff, equipment and infrastructure, necessary to carry out a rapid and effective eradication campaign; there must be an instruction manual detailing all procedures, instructions, and measures, including emergency vaccination plans if deemed necessary, to be implemented in the event of a CSF outbreak; and appropriate staff must regularly receive training and conduct drills in CSF diagnosis, control measures, and communication techniques [12, 13].

EU quarantine decisions with respect to areas affected by CSF would provide the basis for U.S. import restrictions

The APHIS 2000 Risk Analysis took into consideration the mitigating effect of EU control measures existing at the time of the 1997-1998 CSF outbreaks. These measures included quarantine decisions defining the boundaries where control measures where applied and their duration. APHIS estimated the risk of importing CSF in breeding swine, swine semen and swine products from the EU to be low, assuming that future outbreaks did not exceed the severity of that experience in the 1997-1998 epidemic. In that regard, APHIS considers EU regulations defining the boundaries in which control measures are applied to be acceptable but disagrees in regards to duration of quarantine measures.

Current EU regulations allow CSF restrictions in protection zones to be removed no earlier than 30 days after completion of preliminary cleaning and disinfection measures on the infected holding (no earlier than 20 days in surveillance zones) [12, 13]. Measures are lifted only after clinical examinations and serology indicate that the pigs remaining in the zones are free of CSF. Presumably, after restrictions are released, swine from the area could be moved throughout the EU.

APHIS is concerned by observations of recurrence of disease in certain regions shortly after these restrictions have been removed and swine movement commenced. For

example, in December 2001 an outbreak was confirmed in Osoma, Spain 22 days after release of movement restrictions (83 days after depopulation of the last previous outbreak in Spain) [15, 16, 18]. An outbreak in August 2002 in Luxembourg was epidemiologically linked to an outbreak which occurred in June 2002. In fact, the August outbreak occurred 27 days after release of movement restrictions (56 days after depopulation of the affected pigs involved in the June outbreak) [15, 17, 18]. During the 1997-1998 epidemic, the movement restrictions usually remained in force for period exceeding 30 days, and disease spread was extensive. These observations and the EC actions suggest that 30-day duration of restrictions may be insufficient to ensure that the region remains unaffected.

Since APHIS will no longer consider individual EU-15 Member States as regions in which CSF is not known to exist, but instead will place restrictions on exports from the region (EU-15) that are appropriate for a region in which it is expected that CSF outbreaks will continue to occur. The OIE standard that is relevant to this consideration is the standard for a country or zone free of CSF in domestic pigs but with infection in the wild pig population [35]. OIE recommends that, where a stamping out policy without vaccination has been implemented for CSF control, recognition may be acquired 6 months after the last outbreak in domestic pigs.

APHIS concurs with the OIE recommendation to maintain quarantine for 6 months. It considers this restriction period appropriate for the EU-15 and consistent with previously stated intentions. In fact, APHIS stated in the 2000 Risk Analysis its intention to only accept exports from regions that have not experienced an outbreak within 6 months (see pages 13-14 of the APHIS 2002 Risk Analysis [6] and page 16924 of the April 7, 2003 Federal Register notice [1]).

EU-15 certification as to application of appropriate control measures

The April 2003 final rule implemented specific certification requirements for the export of breeding swine, swine semen and swine products from a region of EU to the United States [19, 20]. These requirements are described earlier in this document. In considering the EU-15 as a single region for CSF as proposed, these requirements would become binding on all fifteen EU-15 Member States. In addition, with recognition of EC decisions regarding quarantines established to control subsequent CSF outbreaks, APHIS proposes to require certification by the competent veterinary authority of an EU-15 Member State that exports have fully complied with applicable EU control measures.

Summary of requirements (restrictions) for export to the US

In summary, APHIS will address CSF risk from the EU-15 using the following approach:

1. It will expand the scope of the restrictions defined in the April 2003 final rule (and described previously in this document as mitigations for pork and pork products, breeding swine, and swine semen) to all EU-15 Member States [19, 20].

2. It will require the competent veterinary authority of an EU-15 Member States to provide certification that the swine exported to the United States or the swine from which exported products were derived had never lived in a region when the region was classified as one in which CSF is known to exist. This certification will apply the EC definition of the borders of the relevant region as a restricted zone and recognize EC authority to maintain adequate controls as described previously in this document under the heading, *EU animal health controls*, within and around that zone. Specifically, the restriction zone will encompass protection and surveillance zones established around CSF outbreaks in domestic swine and to encompass infected zones established around CSF outbreaks in wild boar [12-14, 21].

3. For the purposes of export to the United States, it will require the competent veterinary authority of an EU-15 Member State to certify that no commodities originated from a restriction zone established because of CSF in domestic swine for a period of 6 months.

Conclusions

APHIS considers the risk of CSF from breeding swine, swine semen, and fresh pork to be low under the conditions described in this document. APHIS considers the EU control measures to be effective, and its evaluation indicates that the conditions with regard to CSF in the EU-15 have either remained constant or improved, despite the residual CSF reservoir in wild boar and the continuing outbreaks in domestic swine. Since the subsequent observations fall within the expectations of the 2000 Risk Analysis, the risk should still be considered low.

Despite the severity of the outbreak in 1997-1998, the apparent limitations in the EU CSF controls, and the continuing outbreaks in the EU since that time, APHIS concluded that the risk of importing CSF in breeding swine, swine semen, and fresh or frozen pork from the EU-15 was low, as long as it was subject to the APHIS restrictions described previously in this document and the existing EU control measures. Acknowledging that the EU CSF control measures are harmonized and binding on all Member States, APHIS recognizes the EU-15 as a single region for CSF for which restrictions can be placed on exports that are appropriate for a region in which APHIS expects that CSF outbreaks will continue to occur.

Since many of the appropriate restrictions reflect EC quarantine decisions, APHIS is willing to recognize the EC quarantine decisions to define restriction and infected zone boundaries. However, APHIS does not consider a 30-day duration of quarantine to be sufficient for restriction zones. Rather, it considers it necessary to maintain for 6 months the quarantine imposed when CSF has been detected in a domestic swine herd.

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